CLAIMS

1. Nucleotide sequence which regulates the biosynthesis of the flagellar proteins of Helicobacter pylori and is able to hybridize, under conditions of high stringency, with a probe corresponding to a nucleotide fragment from H.pylori which has been amplified using two oligonucleotides having the following sequences:

OLF1bA-1: ATGCCTCGAGGTCGAAAAGCAAGATG

OLF1bA-2: GAAATCTTCATACTGGCAGCTCCAGTC, or able to hybridize, under conditions of high stringency, with these oligonucleotides.

2. Nucleotide sequence of the flbA gene which regulates the biosynthesis of the flagellar proteins of Helicobacter pylori, such as obtained by the steps of:

- screening a genomic library containing the chromosomal DNA of an H.pylori strain with a probe corresponding to a nucleotide fragment from H.pylori which has been amplified using two nucleotides having the following sequences:

OLF1bA-1: ATGCCTCGAGGTCGAAAAGCAAGATG

OLF1bA-2: GAAATCTTCATACTGGCAGCTCCAGTC, or able to hybridize, under conditions of high stringency, with these oligonucleotides.

- recovering the DNA sequences which hybridize with the said probe.

- subcloning the DNA sequences which have been obtained in an appropriate vector of the plasmid type and selecting those modified vectors which hybridize, under conditions of high stringency, with the probe corresponding to the DNA fragment from H.pylori which has been amplified using oligonucleotides OLF1bA-1 and OLF1bA-2,

- sequencing the DNA fragments contained in the plasmid vectors which hybridize with the abovementioned probe and determining the open reading frame contained in these fragments.

3. Nucleotide sequence according to Claim 1 or Claim 2, characterized in that it has the nucleotide sequence depicted in Figure 2.

4. Nucleotide sequence according to any one of Claims 1 to 3, characterized in that it encodes a protein having the amino acid sequence depicted in Figure 2 or an amino acid sequence possessing the same regulatory properties with regard to the biosynthesis of the flagellar proteins of H.pylori as does the abovementioned sequence.

5. Nucleotide sequence according to any one of Claims 1 to 5, which sequence is modified, by deletion, substitution or insertion of bases or of a fragment of a nucleotide sequence, such that the flbA gene is no longer expressed in a host cell or such that expression of the flbA gene in a host cell does not enable the flagella of H.pylori to be biosynthesized and, where appropriate, does not enable the hook protein of H.pylori to be synthesized.

6. Nucleotide sequence corresponding to a fragment of the flbA gene according to any one of Claims 1 to 4, characterized in that it is a fragment of at least 6 nucleotides, preferably of at least 100 nucleotides, which is derived from the flbA gene, preferably delimited by restriction sites which are present in the sequence of the flbA gene.

7. Recombinant nucleic acid, characterized in that it comprises a nucleotide sequence according to any one of Claims 1 to 6, which sequence is modified by the insertion of a cassette containing a marker, for example a gene for resistance to an antibiotic, or a gene for resistance to a heavy metal.

8. Recombinant nucleic acid according to Claim 7, characterized in that the nucleotide sequence according to any one of Claims 1 to 6 is modified by the insertion of a cassette for resistance to kanamycin.

9. Oligonucleotides, characterized in that they are specific for a sequence according to any one of

Claims 1 to 3 and in that they have one of the following sequences:

OLF1bA-1: ATCGTCGAGGTCGAAAAGCAAGATG

OLF1bA-2: GAAATCTTCATACTGGCAGCTCCAGTC

OLF1bA-7: CGGGATCCGGGTTACTAATGGTTCTAC

OLF1bA-8: CGGGATCCTCATGGCCTCTTCAGAGACC

10. Amino acid sequence of the F1bA protein of H.pylori, characterized in that it is encoded by a nucleotide sequence according to either of Claims 1 and 2.

11. Amino acid sequence, characterized in that it is the F1bA protein of H.pylori, having the sequence depicted in Figure 2, or in that it is a fragment of this protein which is recognized by antibodies directed against the F1bA protein.

12. Helicobacter pylori bacterial strain, characterized in that it has an aflagellate phenotype which results from the mutation, by substitution, addition and/or the deletion of bases or of a nucleotide fragment, of the nucleotide sequence according to any one of Claims 1 to 3 of the flbA gene participating in the regulation of the biosynthesis of the flagellar proteins of H.pylori.

13. Bacterial strain according to Claim 12, characterized in that it additionally lacks the hook protein of H.pylori.

14. Recombinant bacterial strain according to Claim 12 or Claim 13, characterized in that it is obtained from the strain N6, which was deposited in the NCIMB on 26 June 1992 under the number NCIMB 40512.

15. Recombinant bacterial strain according to either of Claims 12 and 14, characterized in that it is the strain N6flbA-, which was deposited in the NCIMB on 30 June 1995 under the number NCIMB 40747.

16. Bacterial strain according to any one of Claims 12 to 15, characterized in that it is additionally mutated so that it produces an attenuated urease or else no longer produces urease, the mutation consisting, for example, of a mutation of the nucleotide

sequence of one or more genes selected from among the genes ureA, ureB, ureC, ureD, ureE, ureF, ureG, ureH or ureI.

17. Bacterial extract, characterized in that it is an extract of bacterial strains according to any one of Claims 12 to 15.

18. Bacterial extract according to Claim 17, characterized in that it is obtained after extracting with n-octyl glucoside.

19. Bacterial extract according to Claims 17, characterized in that it is obtained after extracting with PBS or with glycine.

20. Composition for the in vitro detection of an infection due to H.pylori in a sample of biological fluid from a patient, in particular in a sample of serum, which composition includes, as the active principle, a bacterial strain according to any one of Claims 12 to 15 or a bacterial extract according to any one of Claims 17 to 19.

21. Method for the in vitro detection of an infection due to H.pylori in a sample of biological fluid from a patient, in particular in a sample of serum, which method comprises the steps of:

- bringing the sample under test into contact with a bacterial strain according to any one of Claims 12 to 15, or with a bacterial extract according to any one of Claims 17 to 19,
- detecting an immunological reaction between the said bacterial strain and antibodies which are directed against H.pylori and which are present in the sample under test.

22. Immunogenic composition for obtaining antibodies against H.pylori, characterized in that it includes, as the active principle, a bacterial strain according to any one of Claims 12 to 16 or a bacterial extract according to any one of Claims 17 to 19.

23. Immunogenic composition for obtaining antibodies against H.pylori, characterized in that it

includes an amino acid sequence according to either of Claims 10 and 11.

24. Vaccinating composition for obtaining protective antibodies against an infection due to H.pylori, characterized in that it includes, as the active principle, a bacterial strain according to any one of Claims 12 to 16 or a bacterial extract according to any one of Claims 17 to 19.

25. Vaccinating composition for obtaining antibodies against an infection due to H.pylori, characterized in that it includes, as the active principle, antigens which are of the urease type or which participate in the urease activity of H.pylori, in particular antigens encoded by the genes ureA, ureB, ureC or ureD and a protein having an amino acid sequence according to either of Claims 10 and 11.

26. Monoclonal antibodies or polyclonal serum which is/are directed against an amino acid sequence according to either of Claims 10 and 11.

27. Monoclonal antibodies or polyclonal serum which is/are directed against an H.pylori strain according to any one of Claims 12 to 15.

28. Composition for the in vitro detection of an infection due to H.pylori in a biological sample, which composition includes, as the active principle, monoclonal antibodies or a polyclonal serum which is/are obtained against an H.pylori strain of the aflagellate phenotype according to any one of Claims 12 to 15.

29. Use of the nucleotide sequences according to any one of Claims 1 to 9 for preparing immunogenic compositions for obtaining antibodies against H.pylori.

30. Kit for diagnosing antibodies of patients infected with H.pylori, which kit includes a bacterial extract according to any one of Claims 15 to 19 and reagents which are required for demonstrating a reaction of the antigen/antibody type.

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